Clinical aspects of insulin bolus calculators and how patients use them

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The diaTribe Foundation (www.diaTribe.org)

FDA Public Meeting: Regulatory Science Considerations for Software Used in Diabetes Management

November 13, 2014

Thank you!

- Thank you so much for the opportunity to bring a patient perspective to this important meeting!

- We encourage you to think of patients as **partners** to help your team better understand the risks/benefits of all diabetes devices – we're here to help!

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Presentation Outline

- **Patient use of bolus calculators**
- The risks of bolus calculators
- Regulatory considerations
- Needed innovation in insulin bolus calculators

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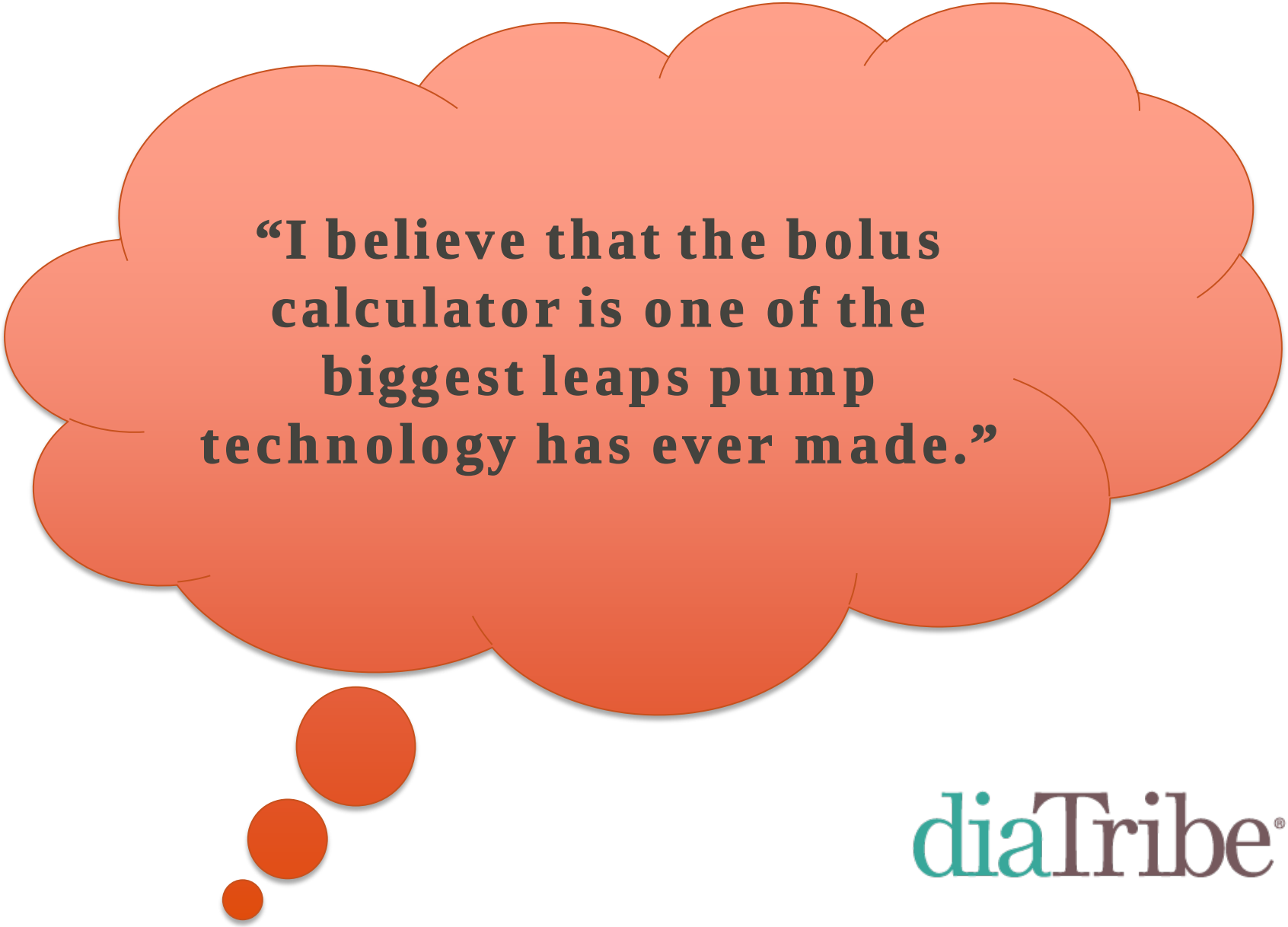
“I believe that the bolus calculator is one of the biggest leaps pump technology has ever made.”

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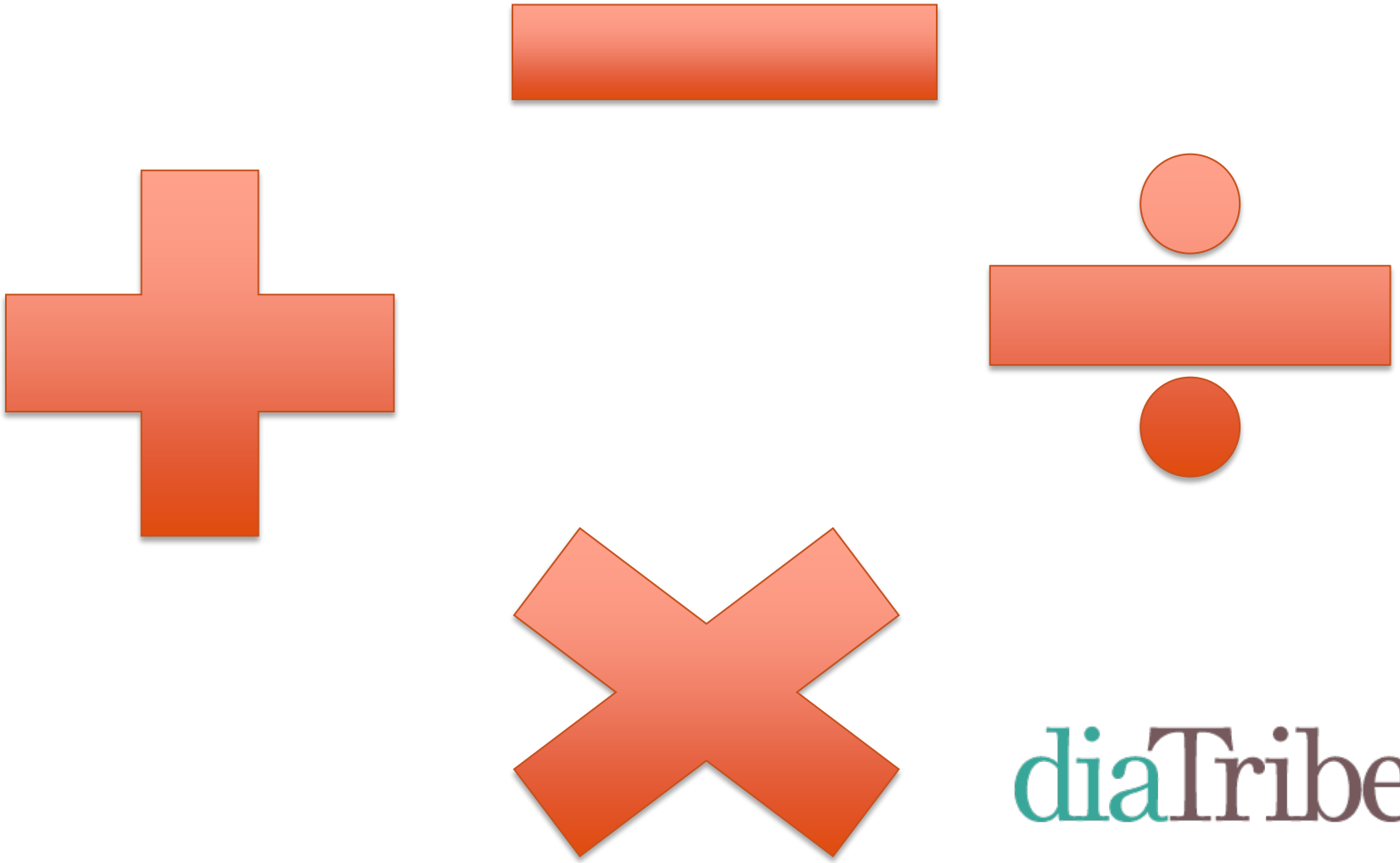
Why are BCs such a huge advance for patients?



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Why are BCs such a huge advance for patients?

A "**simple**" calculation: correction only

BG=165 Target = 100 ISF: 1:35

Correction: 165-100 = 65 / 35 = 1.86 units

Total dose: <u>1.86 units</u>

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Why are BCs such a huge advance for patients?

A "**medium**" calculation: correction + carbohydrates

BG=165 Target = 100 Carbs: 45 ISF: 1:35 ICR: 1:12

Correction: 165-100 = 65 / 35 = 1.86 units
Carbohydrates: 45 carbs/12 = 3.75 units

Total dose: 1.86 + 3.75 = 5.61 units

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Why are BCs such a huge advance for patients?

A "**hard**" calculation: correction + carbohydrates + IOB

BG=165 Target = 100 Carbs: 45 ISF: 1:35 ICR: 1:12
Last bolus taken: 3 units, 3 hours ago
Duration of insulin action (DIA): 4 hours

Correction: 165-100 = 65 / 35 = 1.86 units
Carbohydrates: 45 carbs/12 = 3.75 units
IOB: 3 units/4 hours = 0.75 units left

Total dose: 1.86 + 3.75 -0.75 = 4.86 units

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Why are BCs such a huge advance for patients?

They make the math *much* easier and less subject to human error!

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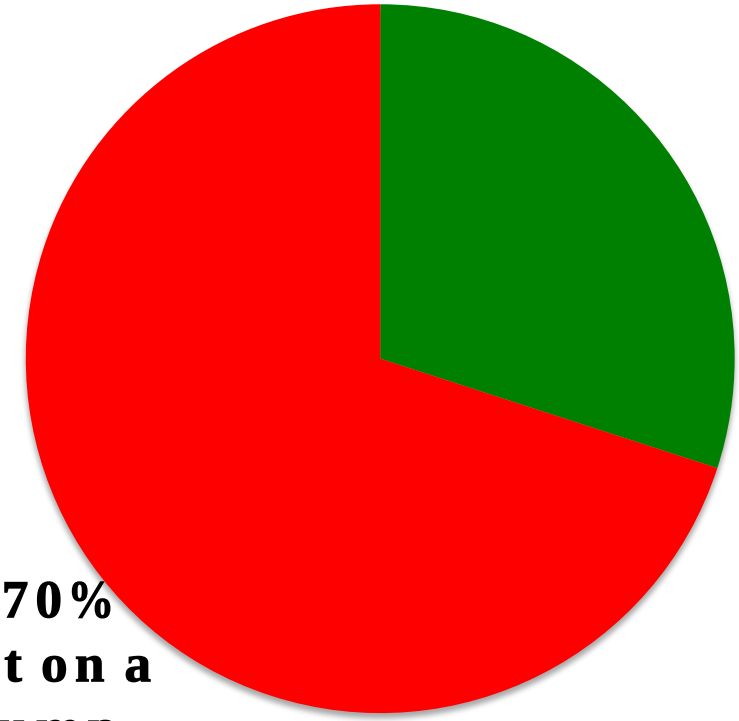
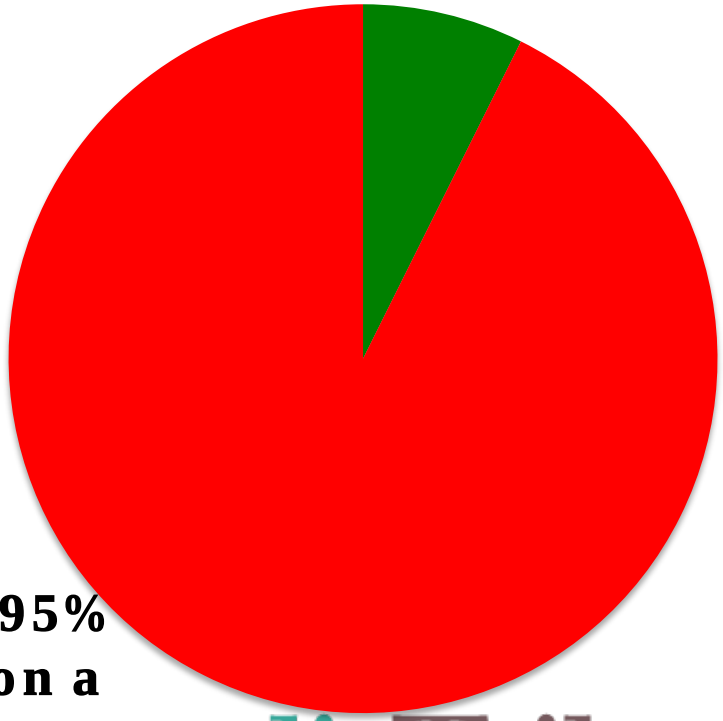
However, most patients don't have access to a bolus calculator

Type 1 - Pump Penetration



~70% Not on a Pump

Basal-Bolus Type 2s - Pump Penetration



~90-95% Not on a Pump

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CDC 2014 Diabetes Fact Sheet; Close Concerns internal estimates

However, most patients don't have access to a bolus calculator

- Roche's Accu-Chek Aviva Expert is the only standalone US meter with a built-in bolus calculator

- Launched Sept 16, 2014

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1. Bolus calculators *reduce* risk for patients and improve quality of life

Patients without access to a bolus calculator:

- Guess/ "ballpark"
- Use "mental" math
- No sense of insulin on board!
- Feel need to eat standardized meals

The real-world impact of “ballparking”

	Actual Scenario	Ballpark Scenario
Current BG Target Last Bolus	165 mg/dl 100 mg/dl 6 units, 3 hours ago	165 mg/dl 100 mg/dl 6 units, 3 hours ago
Settings	ISF: 1:35 , ICR: 1:12 DIA: 4 hrs	
Carbs / insulin needed	45 g / 3.75 units	~60 g / 5 units
Correction	1.86 units	~2 units
IOB	1.5 units remaining	No IOB
Total Dose	**4.11 units**	**7 units**

2. The risks of bolus calculators often trace to poor settings

- ICR, ISF, target, Duration of Insulin action
  - Often end in 5 or 0 for easier math
  - Setup is usually based on very general formulas that don't account for individual variance
  - Rarely change over course of day, though many may benefit from this

Most of these settings are sub-optimal, and the feedback loops are slow/non-existent to improve and optimize them

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3. Risky bolus calculations can be driven by patient errors – Carb Counting

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3. Risky bolus calculations can be driven by patient errors – Not washing hands

"With a sample of 0.3 µl, 1 µg of glucose (the weight of a dust particle) will increase the blood glucose by 300 mg/dl."

- Ginsberg, *J Diabetes Sci Technol* 2009

4. Bolus calculators CANNOT be made 100% fool proof – diabetes is too complicated

22+ Variables Impacting Blood Sugar!

An illustrative calculation

A "**real**" calculation

BG=165 Target = 100 Carbs: 75 ISF: 1:35 ICR: 1:12
Last bolus taken: 3 units, 3 hours ago
Duration of insulin action (DIA): 4 hours

6 hours of sleep last night, woke up multiple times

Less than normal level of activity yesterday

45 carbs includes high fat

Morning bolus

CGM trend arrow: ↑

Total dose: ????

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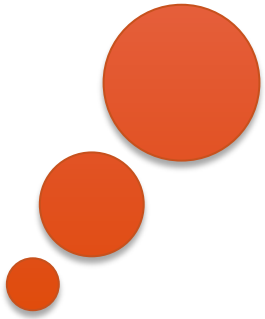
“Insulin pumps precisely deliver inaccurate amounts of insulin.”



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5. The risks of bolus calculators *are much lower* than other aspects of diabetes care

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- **Regulatory considerations**
- Needed innovation in insulin bolus calculators

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Regulatory Focus: Presence vs. Absence

Contains Bolus Calculator
Carries addressable risk

No Bolus Calculator:
Carries Clear Risk

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Recommendations: transparency, simple human factors

- Ideally, patients would have access to clear labeling as to how a particular bolus calculator works (one page, available online)

- Simple software validation and very basic human factors

- **Clinical trials and standardization are likely not necessary:** innovation might be hampered for large and small organizations and patients. This is at a time when the diabetes community needs innovation most.

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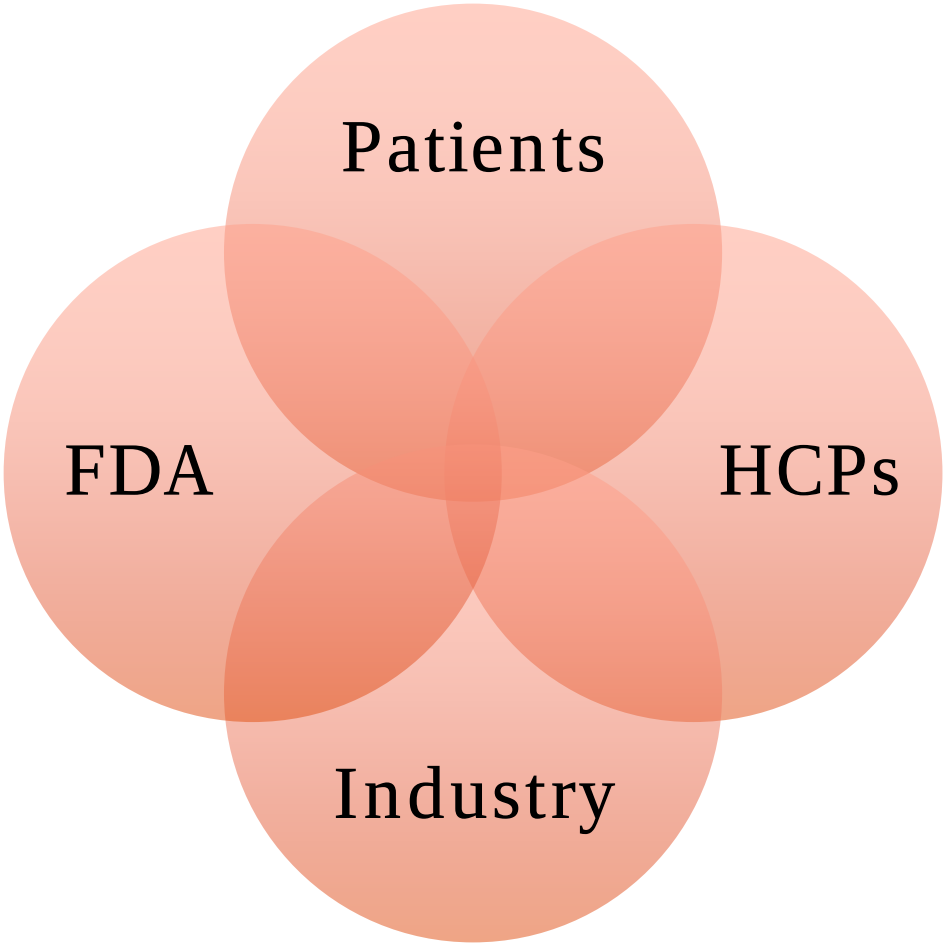
Shared responsibility – no single party should be held liable for 100% safe operation



- Bolus calculators will never be perfect
- Industry, HCPs, patients, and the FDA should jointly **share** the responsibility for proper operation
- Zero risk is probably impossible

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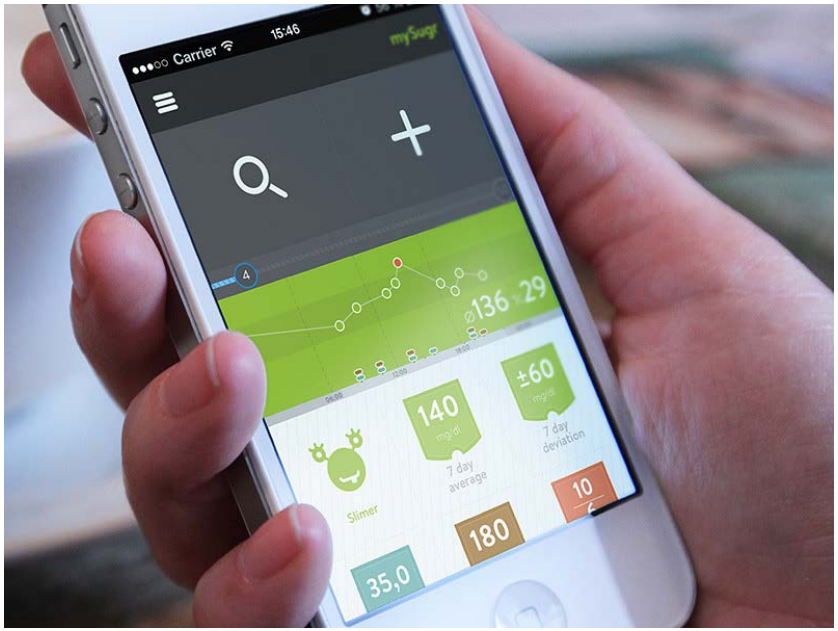
1. More standalone meters and validated apps/software with bolus calculation

- More patients should have access to bolus calculators
- The proper balance between safety/innovation can ensure that happens



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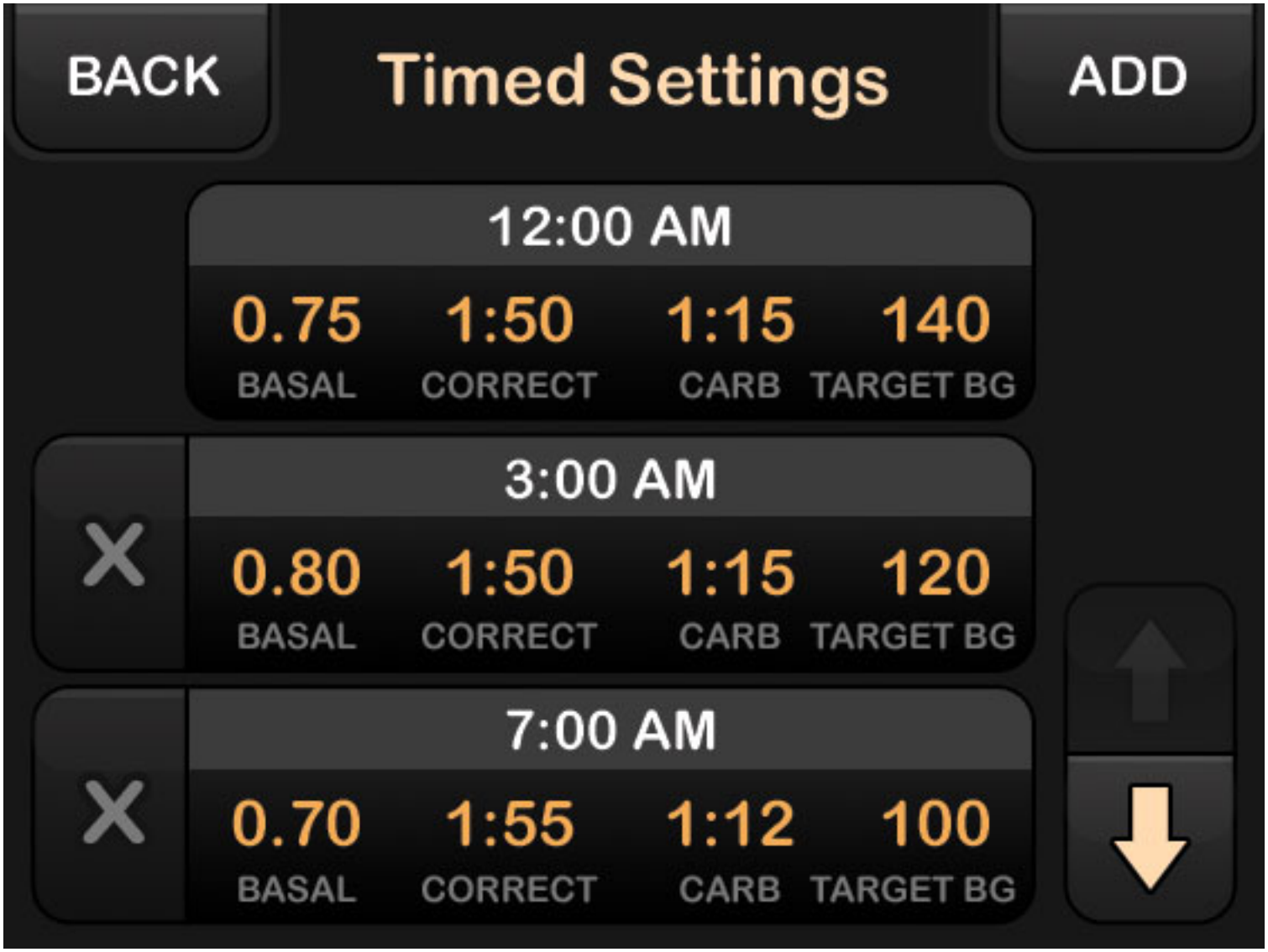
2. Software to optimize bolus calculator settings



3. Addition of CGM trend information

*RT-CGM users with Type 1 and and Type 2 use rate of change arrows to make **significant changes** in their mealtime and correctional insulin doses, much larger than the 10-20% adjustments commonly recommended.*

Trend Arrow	Mean Patient Adjustment to Bolus Dose*	Example Bolus Dose*
→	---	3.0 units
↑	+111%	6.3 units
↑↑	+140%	7.2 units
↓	-41%	1.8 units
↓↓	-47%	1.5 units

Edelman, ATTD 2014; Edelman et al., ADA 2014 – 836-P

4. Treat-to-range controller after meals – a patient safety net!

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Key Takeaway Considerations

- Bolus calculation is filled with complexity and math, even for the most engaged patients.
- Most patients do not currently have access to a pump or meter with a bolus calculator.
- Bolus calculators *reduce* risk for all types of patients – including those with literacy/numeracy issues – and are much less risky than other things patients do every day.
- There is no such thing as a perfectly safe bolus calculator – diabetes is too complicated

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Key Takeaway Considerations

- Ideally, bolus calculators would have clear labeling and human factors to verify that they perform as intended.
- We need more innovation to get bolus calculators into the hands of more patients (standalone meters, software/apps)
- Ultimately, bolus calculators could become more accurate and safer with CGM trend information and treat-to-range control.

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Thank you!

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Committed to improving the lives of people living with diabetes and prediabetes and advocating for action.